

Application No.: 10/799960

Case No.: 58327US004

REMARKS

Claims 1-22 are pending in the application.

Claim 16 is amended herein.

Applicants respectfully request reconsideration of the application in view of the amendments and the following remarks.

Amendment to the Specification

The specification has been amended to correct a typographical error. No new matter is introduced by this amendment.

Amendments to the Claims

Claim 16 has been amended to recite a method of removing a mature tattoo comprising administering to at least a portion of a tattooed region an amount of an IRM compound effective for removing a mature tattoo. This amendment is fully supported by the specification at, for example, from page 7, line 32 through page 8, line 2.

No new matter is introduced by this amendment.

§ 102 Rejections

Claims 16 and 22 are not anticipated by Solis *et al.*

Claims 16 and 22 stand rejected under 35 USC § 102(b) as being anticipated by Solis, R. *et al.*, *Dermaol Surg.*, vol. 28, pp. 83-87 (2002).

M.P.E.P. § 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (quoting *Verdegaal Bros. V. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants submit that Solis *et al.* cannot anticipate Claims 16 and 22 because Solis *et al.* do not set forth each and every element of the claims. Claim 16 has been amended to recite in the body of the claim that the IRM compound is administered in an amount effective for removing a mature tattoo. Claim 22 depends from Claim 16 and, therefore, is also directed to a method of

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removing a mature tattoo. Applicants' specification defines a mature tattoo as a tattoo in which most of the tattoo ink pigment particles have been engulfed by dermal cells. Specification, p. 7, line 33 through p. 8, line 2. Tattoo maturation is thought to take at least 24-72 hours. Specification at p. 8, lines 3-11, and Solis *et al.*, p. 85. Solis *et al.* began treating the tattooed region after only six hours—i.e., while the tattoos were still acute-phase, or immature, tattoos. Indeed, Solis *et al.* admit "it is unknown if our treatment regimen would have any efficacy on more established tattoos where phagocytic engulfment of pigment has occurred." *Id.*, p. 86. Thus, Solis *et al.* explicitly admit that they did not treat mature tattoos and, therefore, cannot anticipate Claims 16 and 22.

The rejection of Claims 16 and 22 under 35 USC § 102(b) as being anticipated by Solis *et al.* has been overcome and should be withdrawn.

§ 103 Rejections

Claims 1-15 are patentable over Anderson in view of Solis *et al.*

Claims 1-15, of which Claim 1 is the only independent claim, stand rejected under 35 USC § 103(a) as being unpatentable over Anderson, R., *Arch. Dermatol.*, vol. 137, pp. 210-212 (2001) in view of Solis *et al.* The Office Action states that Anderson teaches the use of laser energy to remove tattoos by rupturing cells that have engulfed tattoo ink. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to use the laser treatment of Anderson and then the IRM treatment taught by Solis *et al.* before the tattoo ink released from the ruptured cells can be re-phagocytosed.

§ 706.02(j) of the M.P.E.P. states that to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference(s) or combine the reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art references, when combined, must teach or suggest all of the claim limitations.

Applicants submit that the present rejection fails to establish a *prima facie* case of obviousness, is therefore improper, and should be withdrawn. Specifically, Applicants submit

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that one of ordinary skill in the art would not have had a reasonable expectation of success treating a tattoo using the combination of laser therapy and IRM therapy suggested in the Office Action for at least two reasons noted in Anderson. First, ink particles undergo chemical changes upon laser treatment. Anderson, p.210, column 2. Second, other attempts to enhance laser removal of tattoos by activating aspects of the immune system have been unsuccessful. Anderson, discussion of Dierickx *et al.*, pp. 210-211. One skilled in the art would not have had a reasonable expectation that extracellular laser-altered ink of a mature tattoo released as a result of laser treatment would be cleared in the same manner as unaltered extracellular tattoo ink that had never been engulfed by dermal cells.

This view is shared by Solis *et al.*, who state that it was unknown whether the laser treatment of tattoos could re-create the acute-phase tattoo dermal environment that would allow an IRM to be useful in combination with laser therapy to treat mature tattoos. Solis *et al.*, p. 86. Solis *et al.* was published almost one year after Anderson and refers to the Q-switched lasers described in Anderson. Thus, Solis *et al.* had the teachings of Anderson at their disposal and even contemplated the very combination therapy suggested in the Office Action. But, as those of ordinary skill in the art, Solis *et al.* were unable to reasonably expect that the combination of an IRM compound and laser therapy for treating mature tattoos would be effective.

Prior to Applicants' disclosure, no reference offers those skilled in the art a reasonable expectation of success using an IRM compound combined with laser therapy to remove tattoos. The Solis *et al.* reference is a valid representation of the reasonable expectations of those ordinarily skilled in the art of tattoo removal. Absent some evidence that the reasonable expectations of those skilled in the art changed after Solis *et al.* was published, one concludes that at the time the invention was made one of ordinary skill in the art could not have had a reasonable expectation of success treating tattoos using a combination of laser therapy and administration of an IRM compound.

Applicants respectfully submit that the rejection of Claims 1-15 as being obvious under 35 USC § 103(a) over Anderson in view of Solis *et al.* is improper and should be withdrawn.

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Claims 17-21 are patentable over Solis *et al.*

Claims 17-21 stand rejected under 35 USC § 103(a) as being unpatentable over Solis *et al.*

Applicants submit that the present rejection fails to establish a *prima facie* case of obviousness, is therefore improper, and should be withdrawn. Specifically, Applicants submit that Solis *et al.* fails to teach or suggest all of the claim limitations of Claims 17-21. Each of Claims 17-21 depends, directly or indirectly, from Claim 16 and, therefore, includes all of the limitations of Claim 16. As amended, Claim 16 recites administering an IRM compound to a tattooed region having a mature tattoo. The failure of Solis *et al.* to teach, suggest, or set forth all of the limitations of Claim 16—i.e., treating a mature tattoo—is addressed above with respect to the rejection of Claims 16 and 22.

Because Solis *et al.* fails to teach or suggest all of the limitations of Claims 17-21, the rejection of Claims 17-21 as unpatentable over Solis *et al.* has been overcome and should be withdrawn.


Conclusion

In view of the above, Applicants submit that the application is in condition for allowance. Reconsideration of the application and allowance of claims 1-22 is requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that doing so may assist prosecution of this application.

Respectfully submitted,

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Date

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